MAR 3 0 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Boston Scientific/Scimed (BSS)
Atlantis™ SR Pro^2 Coronary Imaging Catheter

Submitted by:

Boston Scientific/Scimed
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538

Contact Person:

Veronica M. Kocken
Regulatory Affairs Specialist II
Tel: (510) 624-1431
Fax: (510) 624-1449
kockenv@bsci.com

Date prepared:

March 4, 2005

Proprietary Name:

BSS Atlantis™ SR Pro^2 Coronary Imaging Catheter

Common Name(s):

Ultrasound Diagnostic Imaging Catheter
Diagnostic Intravascular Catheter (74DQO)
Diagnostic Ultrasonic Transducers (90ITX)

Classification Name(s):

Diagnostic Intravascular Catheter, 21 CFR Part 870.1200 (74DQO)
Diagnostic Ultrasonic Transducer, 21 CFR Part 892.1570 (90ITX)

Predicate Device(s):

The BSS Atlantis™ SR Pro^2 Coronary Imaging Catheter is substantially equivalent to the following device:

Product	510(k)	Clearance Date
Atlantis™ SR Plus Coronary Imaging Catheter	K010707	March 29, 2001

Description of the Device:

The catheters included in the Atlantis™ family of intravascular ultrasound coronary imaging catheters (i.e., SR, SR Plus, SR Pro, and SR Pro^2) are designed to be used with the Clearview® Ultra with High Frequency (HF) option, Galaxy™ or Galaxy™ 2 intravascular ultrasound imaging instruments. These catheters are comprised of two main assemblies:

- Imaging core
- Catheter body

The catheter body is comprised of three sections:

- Distal lumen
- Proximal lumen
- Telescoping section

The imaging core is composed of a hi-torque, flexible, rotating drive shaft with a radially-looking 40 MHz ultrasonic transducer at the distal tip. An electro-mechanical connector interface at the proximal end makes the connection to the Motor Drive Unit (MDU) which is in turn connected to the imaging system (e.g., Galaxy™ system). The MDU-Catheter interface consists of an integrated mechanical drive hub and an electrical connection.

The catheter body has a distal guidewire lumen with proximal exit port at approximately 1.5 cm from the distal end. The catheter body is attached to the telescope section via a male/female luer connection. A radiopaque (RO) marker is embedded in the catheter body at 0.5 cm from the distal tip. In addition, an insertion depth indicator is located on the catheter body at 105 cm, corresponding to femoral insertions.

Within the catheter body, the distal lumen and proximal lumen sections comprise the "working length" of the catheter, and the telescoping section remains outside

of the guiding catheter. The telescoping section allows the imaging core to be advanced and retracted for 15 cm of linear movement. The corresponding movement of the transducer occurs from the proximal end of the wire exit port, to the proximal end of the distal lumen.

A flush port with a one-way valve is used to displace air near the transducer. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way valve helps retain saline in the catheter during use.

Atlantis SR Pro^2 catheter

The Atlantis SR Pro^2 catheter modifications are being implemented to improve performance and functionality of the catheter. The Atlantis™ SR Pro^2 catheter is the same as the Atlantis™ SR Plus catheter, except for the following changes:

- Inclusion of a hydrophilic coating (Bioslide™) to the distal 230mm portion of the catheter sheath. The purpose of the hydrophilic-coating is to improve catheter lubricity, thus reducing catheter frictional resistance during introduction into the coronary vessel.

- A change is made to switch from Dymax adhesive 1-20271-G to Dymax adhesive 191 M-T in the Female Telescope assembly. The Dymax adhesive 191 M-T is currently being used within the same product for the Male Telescope assembly. The reason for the change is to reduce material variability in manufacturing of the catheter, and to limit the types of adhesives used in the device. The change is being implemented based on acceptable results from verification testing, in which the bond strength met the acceptance criteria. The female telescope assembly is a section of catheter that remains external to the patient during the application of the device.

Intended Use/Indications:

The Atlantis SR Pro^2 catheter is intended for ultrasound examination of coronary intravascular pathology ONLY. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Device Technology Characteristics an Comparison to Predicate Device:

The BSS Atlantis™ SR Pro^2 Coronary Imaging Catheter utilizes the same basic catheter design as the predicate device, the BSS Atlantis™ SR Plus Coronary Imaging Catheter, cleared in March 29, 2001, and the current Atlantis™ SR Pro, cleared via internal documentation (letter-to-file dated, February 14, 2003 and January 27, 2004). These devices have the same intended use, use the same operating principal, incorporate that same basic catheter design, have the same shelf life, and are packaged using the same materials and processes. The two modifications from the Atlantis™ SR Pro to the Atlantis™ SR Pro^2, is the addition of lubricous hydrophilic coating (Bioslide™) to distal segment (230mm minimum) of the catheter sheath, and the use of Dymax 191 M-T adhesive on the telescope assembly.

Non-clinical Test Results:

Bench and biological safety testing demonstrate that the Atlantis™ SR Pro^2 imaging catheter meets or exceeds the performance requirements and is safe and effective for its intended use.

Bench Testing:

Bench testing was performed to evaluate the physical integrity and functionality of the catheter. This testing included dimensional testing, sheath bond tensile testing, and a variety of functional and performance testing of the sheath assembly, the telescope assembly, and the final sterile device. The results demonstrated that the device satisfies all performance, physical, and functional requirements.

Biological Safety Testing:

The Atlantis™ Pro^2 catheter was subjected to a series of biocompatibility tests per ISO 10993, bioburden, endotoxin, sterility assurance, and latex testing. The results of the biocompatibility testing demonstrate that the catheter is acceptable for its intended use.

Acoustic Output Testing:

Acoustic Output testing was not required for the Atlantis™ SR Pro^2, as the addition of hydrophilic coating to the distal sheath of the catheter will not change the Acoustic Output measurement of the transducer, thus undetectable to the performance of the catheter.

Per the FDA Guidance, *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 30 1997),* Acoustic Output measurements for the Atlantis™ SR Pro^2 catheter remains unchanged from its predicate device, the Atlantis™ SR Plus catheter and the Atlantis™ SR Pro catheter for which a letter-to-file was documented.

Table 2 of this submission provides the Acoustic Output equivalency comparison, followed by a rationale for not conducting Acoustic Output testing on the Atlantis™ SR Pro^2 coronary catheter.

Conclusion:

The BSS Atlantis™ SR Pro^2 Coronary Imaging Catheter utilizes the same design features and has the same intended use as the predicate device, the Atlantis™ SR Plus Coronary Imaging Catheter. The tests support a determination of substantial equivalence of the modified device, the Atlantis™ SR Pro^2 Coronary Imaging Catheter to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2005

Boston Scientific Corp.
IVUS Technology Center
c/o Ms. Veronica Kocken
Regulatory Affairs Specialist II
47900 Bayside Parkway
Freemont, CA 94538-6515

Re: K050577
Trade Name: Atlantis SR Pro^2 Coronary Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: II (two)
Product Code: DQO
Dated: March 04, 2005
Received: March 07, 2005

Dear Ms. Kocken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K050577

Device Name: **Boston Scientific/Scimed, Atlantis™ SR Pro^2 Coronary Imaging Catheter**

Indications for Use: The Atlantis SR Pro^2 catheter is intended for ultrasound examination of coronary intravascular pathology ONLY. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/ OR Over the counter Use _____ Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Summerow

on Sign-Off)
on of Cardiovascular Devices
Number K050577